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Ambient Water Quality Criteria Document Addendum for Antimony

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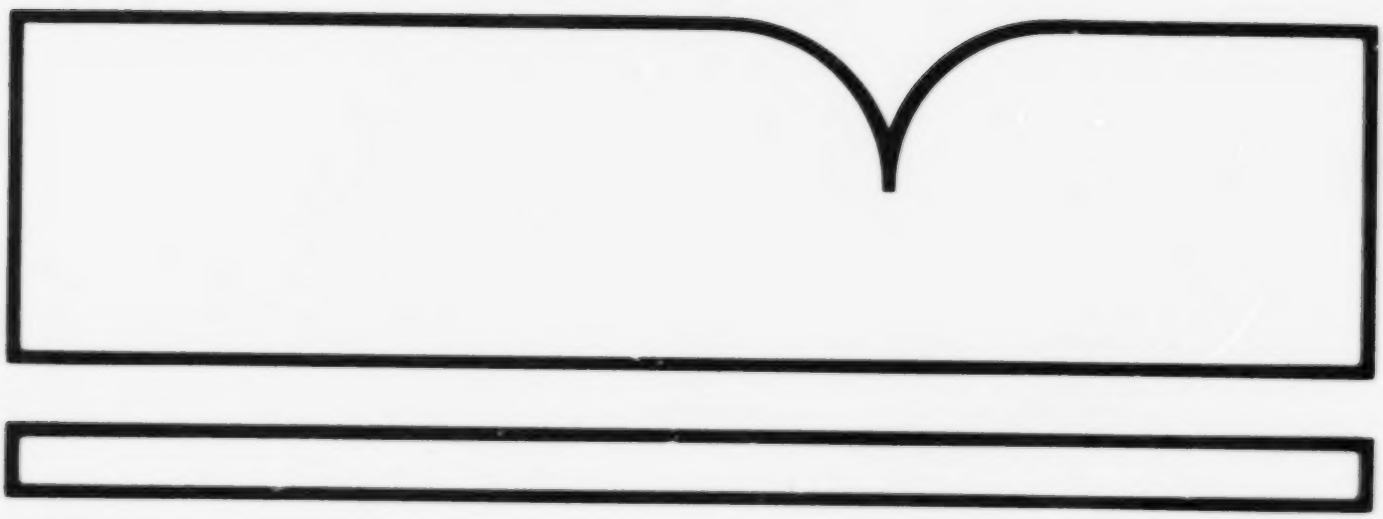

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Prepared by

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PREFACE

Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information from Agency files and Program Offices. The first draft of this addendum was prepared by Syracuse Research Corporation under contract no. 68-C8-0004.

TABLE OF CONTENTS

	Page
INTRODUCTION	1
REVIEW OF NEW DATA	4
Toxicologic/Carcinogenic Effects	4
Bioconcentration Factor (BCF)	6
QUANTIFICATION OF EFFECTS	7
EXISTING STANDARDS AND CRITERIA	9
REFERENCES	10

LIST OF ABBREVIATIONS

ADI	Acceptable daily intake
BCF	Bioconcentration factor
ECG	Electrocardiogram
GOT	Glutamic oxaloacetic transaminase
GPT	Glutamic pyruvic transaminase
LOAEL	Lowest-observed-adverse-effect level
LOEL	Lowest-observed-effect level
NOAEL	No-observed-adverse-effect level
ppm	Parts per million
RfD	Reference dose
RQ	Reportable quantity
SNARL	Suggested no-adverse response level
TLV	Threshold limit value
TWA	Time-weighted average

INTRODUCTION

Under Section 304(a)(1) of the Clean Water Act of 1977 as amended in 1987, the U.S. EPA is required to publish criteria for water quality accurately reflecting the latest scientific knowledge regarding the effects on health and welfare that may occur from the presence of pollutants in any body of water, including groundwater. In accordance with the 1977 act, Ambient Water Quality Criteria Documents (AWQCDs) were developed in 1980 for 65 toxic pollutants or classes of pollutants listed under Section 307(a)(1).

These addenda are intended to serve as an update of the original AWQCDs. The addenda provide the Agency with the latest scientific assessments of potential health hazards associated with these pollutants and serve as guidelines for modifying the current (1980) AWQCDs.

The human health criteria in these addenda are based on Agency verified risk assessment values when available. These values consist of reference doses (RfD) for those chemicals believed to be systemic toxicants (i.e., do not induce cancer) and cancer risk factors for those thought likely to cause cancer in humans. The verification process consists of a review and consensus of risk assessment values provided by an Agency workgroup consisting of scientists from each of the major Agency offices. Assessments for noncarcinogens are verified by the RfD workgroup and those for carcinogens are verified by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) workgroup. If such values are not available, the criteria are based on the most recent Agency health assessment. In the absence of any appropriate Agency value, RfD values or cancer risk factors are derived by current Agency methods if adequate new data are available, and criteria are recommended based on the proposed RfD or risk factor.

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is derived by dividing a NOAEL or LOAEL for subchronic or chronic exposure by standard uncertainty factor(s) times an additional uncertainty factor:

$$RfD = \frac{\text{NOAEL or LOAEL}}{UF(s) \times UF}$$

The standard uncertainty factors are applied to reflect the various types of data used to estimate RfDs. An uncertainty factor of 10 is used to account for variations in human sensitivity when extrapolating from valid human studies involving long-term exposure of average, healthy subjects. An additional 10-fold factor is used for each of the following: to extrapolate from long-term animal studies to the case of humans, to extrapolate from subchronic animal studies to chronic exposure, and to extrapolate from a LOAEL to a NOAEL. An additional uncertainty factor of >0-10 may be applied to reflect professional assessment of the uncertainties of the study and data base not explicitly addressed by the standard uncertainty factors (i.e., completeness of the overall data base). The default value for the additional uncertainty factor is 1.

In assessing the carcinogenic potential of a chemical, the U.S. EPA classifies the chemical into one of the following groups according to the degree of evidence in epidemiological studies and animal studies: Group A - Human Carcinogen; Group B - Probable Human Carcinogen [limited evidence in humans with or without sufficient evidence in animals (Group B1) or inadequate evidence in humans with sufficient evidence in animals (Group B2)]; Group C - Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); Group D - Not Classifiable as to

Human Carcinogenicity (inadequate or no evidence); Group E - Evidence of Noncarcinogenicity for Humans. Quantitative carcinogenic risk assessments are performed for chemicals in Groups A and B, and on a case-by-case basis for chemicals in Group C. Upper-bound cancer unit risks (slope values) are estimated through the use of mathematical extrapolation models. Most commonly for animal data, the linearized multistage model with a 95% upper confidence limit is used to provide a low-dose estimate of cancer risk. The cancer risk is characterized as an upper-limit estimate (i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-limit estimate and in fact may be lower). Alternative risk models to the multistage model, such as the one-hit, Weibull, Logit or Probit model, are available and may be used when the evidence indicates that they may be more appropriate. In the absence of such evidence, the Agency recommends the linearized multistage model to provide consistency of approach and an upper-bound on the potential carcinogenic risk. In the case where human data are used for quantitative risk assessment, an upper-bound estimate rather than a 95% upper-bound estimate is used when low-dose linearity is assumed.

In the development of this Addendum to the AWQCD on antimony, recent Agency assessments have been consulted. A computerized literature search was conducted to cover studies published more recently than the latest Agency assessment (i.e., published in 1985 to 1988). New key studies have been evaluated.

REVIEW OF NEW DATA

Toxicologic/Carcinogenic Effects

Female normotensive (not otherwise specified) albino rats (30/group) were administered antimony trichloride at 0, 0.1 or 1 mg/dℓ (0, 1 or 10 ppm) in drinking water from the 1st day of pregnancy until weaning of the pups (22 days after delivery) to evaluate the effect of antimony on development of vascular reactivity in the pups (Rossi et al., 1987). The pups (10/dam) received antimony trichloride at 0, 1 or 10 ppm in their drinking water from weaning to day 60. The dams showed a dose-related significant ($p<0.05$) decrease in body weight on day 20, but not day 10 of gestation. There were no significant ($p<0.05$) changes in maternal or offspring systolic arterial blood pressure, length of gestation or number of pups/litter. The pups in the high-dose group had significantly ($p<0.05$) reduced body weight from days 10-60, but showed no macroscopic teratogenic effects. Pre- and postnatal exposure to antimony trichloride did not significanty ($p<0.05$) affect pressor response to transient carotid artery occlusion. Pressor response of 60-day-old pups to l-noradrenalin and l-isoprenaline (hypertension-inducing drugs) was significantly ($p<0/05$) decreased in both antimony trichloride-treated groups compared with untreated controls, and response to acetylcholine (hypotension-inducing) was significantly ($p<0.05$) decreased only in the high-dose pups at 60 days.

In another study, male Wistar rats were divided among one control and three treated groups (Hiraoka, 1986). The treated groups were fed diets containing 0.1% (w/w) metal antimony, 1.0% (w/w) antimony or 1.0% antimony trioxide for 12 weeks (0, 0.1%, 1.0% or 1.0% antimony). The rats were evaluated at 0, 4 and 12 weeks post-exposure for body weight gain, organ weights, hematological and limited blood biochemical endpoints. There were no effects on behavior, general appearance, blood hemoglobin concentration,

GOT activities or A:G ratio. Elevated GPT and decreased hematocrit and total blood protein were observed in rats fed the diet containing 1% metallic antimony <4 weeks after exposure. Body weights of rats fed diets containing 1% metallic antimony and 1% antimony trioxide were depressed after 12 weeks of exposure, but not after the 12-week recovery period. The abstract stated that some significant changes in organ weights (not specified) were observed in antimony treated rats, however the complete paper was not available for review.

The carcinogenicity of antimony was recently reviewed by U.S. EPA (1987a). A briefly reported retrospective epidemiological study of antimony process workers associated lung cancer with occupational exposure to antimony (Davies, 1973). Schroeder et al. (1970) provided Long-Evans rats with drinking water containing 5 ppm antimony (see next section) and Kanisawa and Schroeder (1969) provided CD-1 (male and female) mice with drinking water containing 5 ppm antimony in lifetime studies and concluded that neither rats nor mice exhibited a carcinogenic response. In an inhalation study (ASARCO, Inc., 1980; Watt, 1980, 1981, 1983), a statistically significant increase in the incidence of lung tumors was observed in female Sprague-Dawley rats intermittently exposed to antimony from antimony trioxide at 4.2 mg/m^3 but not at 1.6 mg/m^3. The data were not sufficient for quantitative estimation of carcinogenic potency, but antimony was assigned to EPA Group B2: probable human carcinogen (U.S. EPA, 1987a). Current data are inadequate to assess the potential carcinogenicity of ingested antimony.

Bioconcentration Factor (BCF)

The BCF value of 1 determined in U.S. EPA (1980) was reevaluated in Stephan (1983). A new BCF of 0.5 was derived. Pertinent new information regarding the BCF value for antimony is currently undergoing Agency review. The BCF value of 0.5 (Stephan, 1983) will be used until this evaluation has been completed.

QUANTIFICATION OF EFFECTS

The 1980 ambient water quality criteria (U.S. EPA, 1980) for human health for antimony were based on a lifetime study in which groups of at least 50 male and 50 female Long-Evans rats were provided drinking water containing antimony at 0 or 5 ppm from antimony potassium tartrate (Schroeder et al., 1970). Endpoints monitored included mortality, body weights, blood pressure, serum chemistries including glucose, urinalysis and tumor incidence. Rats that died during the study were necropsied and gross lesions were examined histopathologically. Treated rats of both sexes had significantly decreased survival and decreased nonfasting serum glucose, compared with controls. Treated males had elevated serum cholesterol and treated females had decreased serum cholesterol. The 5 ppm antimony level was designated a LOEL, but was considered to be close to the NOAEL. U.S. EPA (1980) estimated that the rats weighed 0.3 kg, assumed a drinking water consumption value of 0.025 ℓ/day and applied an uncertainty factor of 100 (10 for inter- and 10 for intraspecies variation) to derive an ADI for antimony of 4.17 µg/kg/day. Assuming a human body weight of 70 kg, daily drinking water consumption of 2 ℓ/day, daily fish and shellfish consumption of 0.0065 kg/day and a BCF of 1, U.S. EPA (1980) derived water criteria of 145 µg/ℓ for consumption of water and fish and shellfish and 45 mg/ℓ for consumption of fish and shellfish alone.

The Schroeder et al. (1970) study was also used as the basis for the verified RfD currently on IRIS (U.S. EPA, 1985a). In the RfD derivation, the 5 ppm concentration was equivalent to a dosage of 0.35 mg/kg/day based on an estimation of drinking water consumption. Although Schroeder et al. (1970) did not calculate a dosage for antimony, U.S. EPA (1987a) noted that

another report from this laboratory (Kanisawa and Schroeder, 1969) provided an estimate of drinking water consumption by rats in parallel studies from which the dosage of 0.35 mg/kg/day can be estimated. Application of an uncertainty factor of 1000 (10 for interspecies variation, 10 for intraspecies variation and 10 to estimate a NOAEL from a LOAEL) resulted in an RfD of 0.00035 mg/kg/day, which was rounded to 0.0004 mg/kg/day. Applying the assumptions discussed above, and the BCF of 0.5 derived in Stephan (1983), new ambient water quality criteria of 14 µg/ℓ for consumption of water, fish and shellfish and 8.6 mg/ℓ for consumption of fish and shellfish alone can be derived.

A more recent paper by Rossi et al. (1987) identified a dose-related reduction in body weight gain in dams exposed to 1 and 10 ppm antimony trichloride in drinking water throughout gestation. In addition, high-dose pups had reduced body weights and the response of pups to hyper- and hypotension-inducing drugs was altered. Because food and water consumption data were not provided, it was not possible to determine if the effects on body weight reflect toxicity of the chemical or reduced food and/or water intake. Using a formula for estimating drinking water consumption (0.049 ℓ/day) for rats weighing 350 g (U.S. EPA, 1986), dosages of antimony trichloride of 0.14 and 1.4 mg/kg/day can be estimated. Corresponding dosages of antimony are 0.07 and 0.75 mg/kg/day. These data suggest an effect on body weights at dosages lower than that used by Schroeder et al. (1970) in which there were no effects on body weight in a much longer study. It is possible that antimony trichloride is more toxic to rats than antimony potassium tartrate. Additional studies may be warranted in order to clarify this effect level.

EXISTING STANDARDS AND CRITERIA

NAS (1980) determined that data were insufficient for derivation of 1-day, 7-day or chronic SNARLs for antimony. U.S. EPA (1987b) listed antimony as a contaminant in drinking water required to be regulated by the 1986 amendments to the Safe Drinking Water Act; however, regulations are not yet available.

Arzamastsev (1964) determined the taste threshold for either trivalent or pentavalent antimony at 0.6 mg/ℓ.

The ACGIH (1987) TLV-TWA recommendation, OSHA (1985) standard and NIOSH (1978) criteria are all set at 0.5 mg/m³. ACGIH (1986) stated that the TLV should protect against ECG effects, dermatitis, irritation of the mucous membranes and pneumoconiosis.

The final RQ for release into the environment is 5000 pounds (U.S. EPA, 1988).

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